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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,548	08/25/2003	Javier Saez-Valero	104664-50037	5163

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
10/648,548	SAEZ-VALERO ET AL.	
Examiner	**Art Unit**	
Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S. 0. C.

RESPONSE TO AMENDMENT

The amendment and response filed 3-28-05 have been entered into the record. Claims 1-29 have been cancelled. Claims 30-36 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The priority has been updated and the requirement is withdrawn.

The objection of claims 20-25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of the cancellation of the claims.

The rejection of claims 20-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the cancellation of the claims.

The rejection of claims 19-29 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the cancellation of the claims.

The rejection of claims 19-29 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the diagnosis of Alzheimer's disease in a patient comprising the steps of providing a sample of biological fluid from a patient, detecting the presence of total butyrylcholineserase in the sample, detecting the

presence of butyrylcholinesterase unbound to both concanavalin A (conA) and *Lens culinaris* (LCA) lectins, determining the percent butyrylcholinesterase unbound to both conA and LCA wherein a increase in the percent of butyrylcholinesterase unbound to conA and a decrease in the percent of butyrylcholinesterase unbound to LCA as compared to normal is indicative of Alzheimer disease and further wherein the total and unbound butyrylcholinesterase is determined by enzymatic activity or monoclonal antibody binding, it does not reasonably provide enablement for patterns of altered glycosylation of butyrylcholinesterase in general or relative binding affinities to any lectin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims is withdrawn based on the cancellation of the claims.

The rejection of claims 19-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the cancellation of the claims.

New Rejections Based on Amendment

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the claims recite the correlative step (4) of "probable presence of Alzheimer's disease in the patient as a direct correlation to the amount of on unbound butyrylcholinesterase, wherein the probability of the presence of Alzheimer's disease increases as the amount of unbound butyrylcholinesterase increases. The specification as originally filed does not find any determination of probability and no relationship of probability and specific increased with the probable presence of Alzheimer's disease. Applicants are specifically cautioned against adding language to the specification that is not supported by the original disclosure.

Claims 30-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims now recite a correlation as set forth in step (4) of claim 30. The claims indicate that the "probability of the presence of Alzheimer's disease increases as the amount of unbound butyrylcholinesterase increases" and "probable Alzheimer's disease". First, there is no support in the specification for "probable Alzheimer's disease" and is in conflict with the preamble of the claim. This issue is best resolved by Applicants pointing to the specification by page and line number where written description support for "probable Alzheimer's Disease" can be found. With respect to the recitation of "wherein the probability of the presence of Alzheimer's disease increases as the amount of unbound butyrylcholinesterase increases" is in fact a risk assessment. Probability is defined in medicine as a measure, ranging from 0 to 1, of the likelihood of truth of a hypothesis or statement (see Stedman's Medical Dictionary attached hereto) and risk is the probability that an event will occur (see Stedman's Medical Dictionary attached hereto). The specification does not convey either probability or risk as defined in the art. The concept of probability or risk is not conveyed by the written description of the specificaiton as filed. There is no correlation of levels of unbound butyrylcholinesterase and probability of Alzheimer's disease as measured by standard methods in the art. Probability is the risk of having the disease. There is in no instance any written description in the specification as originally filed that teaches probability of Alzheimer's disease. All comparisons were based on comparing normal to patients with Alzheimer's disease. This is not a probability determination. There are no probability statistics assigned to different levels or increased levels of butyrylcholinesterase as instantly claimed. What is the probability for

increased levels? What number or risk is assigned to the specific increase observed? The specification does not provide for this concept. As such, the correlation as it relates to probability determination as a result of increased levels is not conveyed by the specification as filed and is deemed new matter. This issue is best resolved by Applicants pointing to the specification by page and line number where specific written description and conception of probability determination based on different levels is contemplated and assessed.

Claims 30-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 30 and dependent claims 31-36, the claims are confusing because the preamble of claim 30 conflicts with the correlation step (4). The preamble recites diagnosis of Alzheimer's disease and the correlation step assesses probability (i.e. risk) of disease. The preamble is absolute and the correlation step is a risk of disease. Therefore, the correlation step is in conflict with the goal of the preamble.

As to claims 31-36, these dependent claims are confusing because they begin with the recitation of the indefinite article "A" meaning any method, but then attempt to further limit the method to particular steps or procedures. Amendment of these dependent claims to change "A" to "The" would obviate this issue.

Status of Claims

Claims 30-36 stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645